

OPTN Pediatric Transplantation Committee

Meeting Summary

July 13, 2022

Conference Call

Evelyn Hsu, MD, Chair

Emily Perito, MD, Vice Chair

Introduction

The Pediatric Transplantation Committee (the Committee) met via Citrix GoTo teleconference on 7/13/2022 to discuss the following agenda items:

1. Welcome to New Committee Members & Orientation
2. Review of Pediatric Estimated Post-Transplant Survival (EPTS) Validation Data Request Results

The following is a summary of the Committee's discussions.

1. Welcome to New Committee Members & Orientation

The Committee welcomed new members whose committee term started on 7/1/22. The Committee received an orientation, which included an overview of the following:

- OPTN Governance Structure
- Policy Development Process
- Pediatric Heart ABO-incompatible (ABOi) Project Update
 - Proposed Policy Modifications
 - Expand access to all status 1A, 1B, and 2 candidates who are registered prior to turning 18 years old
 - Registered prior to turning one year old: no policy changes
 - Registered after turning one year old, but before turning 18 years old:
 - Replace use of isohemagglutinin titer of 1:16 with 1:8 and create two groups of eligible candidates
 - Those whose titers are less than or equal to 1:8 and without antibody reduction strategy are designated as secondary blood type match
 - Those whose titers are greater than 1:8 or have received AB reduction therapy are designated as tertiary blood type match
 - Update deceased donor allocation tables to include new group of eligible candidates – tertiary blood type match – and maintains equitable prioritization
 - Status Update
 - Compliance review process identified compliance issue
 - What evidence demonstrates that candidates in secondary classification should be prioritized ahead of tertiary candidates?
 - Accommodating Heart-Lung allocation needed
 - Re-convene Pediatric Heart ABOi Workgroup
 - Submit revised proposal for public comment as part of January 2023 cycle and OPTN Board of Directors approval as part of June 2023 meeting

- Roles and Support for Committee Members

Summary of discussion:

Pediatric Heart ABOi Project Update

The Chair inquired if members of the Pediatric Heart ABOi Workgroup could explain how they crafted the proposed policy modifications from their experiences in their own practice and knowing about these issues in the literature. A member stated that they recognized that the science had advanced to the point that centers would feel comfortable performing ABOi transplants and there would be patients who had previously received an ABOi heart transplant and may need a re-transplant. Members of the Pediatric Heart ABOi Workgroup looked at what was being published or had been published recently and spent time with the current policy digesting what it required in order to work with staff throughout the policy development process.

A member stated that this has been a learning experience for them and made them think of not only the biology of ABOi heart transplants but also policy implications.

A member inquired if the change in titers, from 1:16 to 1:8, will change allocation for heart candidates between one and two years old. A member stated that any candidate over age one will become eligible for ABOi heart transplantation and if they have a titer less than or equal to 1:8, then they would fall into the secondary classification which would be akin to where those one- to two-year-old candidates are in current heart allocation. This opens a pathway to candidates who have a high titer, above 1:8, so they could still get an ABOi heart transplant.

A member stated that they thought 1:8 was more conservative than 1:16, so they were concerned that the titer change might slightly disadvantage candidates who may have been eligible for ABOi heart transplant before this change. A member explained that candidates with a titer of 1:16 will still be eligible for ABOi heart transplant, just one classification behind what they are now.

Roles and Support for Committee Members

A member emphasized that the pediatric voice is not always identified or listened to and most transplants performed in this country are adult transplants; however, children don't have a lot of people to speak up for them and it is the Committee's responsibility to ask how proposals will affect kids or what the downstream effect on kids will be.

A member stated that they agreed and mentioned that they thought the Committee should be a gateway committee for all the organ-specific committees and should be able to provide feedback on all their proposals.

The Chair emphasized that the Committee's participation on the Policy Oversight Committee (POC) is also important in identifying projects that will need to be reviewed by the Committee, hopefully early in the process.

There was no further discussion.

2. Review of Pediatric Estimated Post-Transplant Survival (EPTS) Validation Data Request Results

The Committee reviewed the results of the Evaluating Predictive Ability of Estimated Post-Transplant Survival (EPTS) in Pediatric Kidney Recipients data request.

Data summary:

Background

Current kidney and pancreas continuous distribution modeling includes longevity matching through the use of EPTS and EPTS is not currently calculated for pediatric candidates. There have been ongoing discussions as to whether or how EPTS should be used for pediatric kidney candidates in the kidney and pancreas continuous distribution framework.

There are two proposals:

- Apply existing EPTS formula to pediatric patients
- Assign all pediatric patients an EPTS of one
 - This would result in pediatric patients getting additional priority

Committee members with pediatric kidney expertise suggested assigning all pediatric patients an EPTS score of one in the kidney and pancreas continuous distribution modeling and determined they would use the results of this data request to justify their decision.

Data Request Goal

Determine whether EPTS has sufficient predictive ability to justify applying it to pediatric patients in the kidney and pancreas continuous distribution framework.

Methods

- Use a cohort of all pediatric patients transplanted from 2001-2011
- Calculate EPTS on these patients
- Create a cox model
- Calculate the c-statistic of this model

Results

- Distribution of EPTS in cohort
 - Minimal variance in EPTS
 - 87 percent have an EPTS less than or equal to three
 - Highly unlikely to observe significant c-statistic, regardless of cohort selected
- C-Statistic
 - C-statistic for this model was 0.505
 - 95% confidence interval was (0.49, 0.53)
 - This model is not significantly predictive

Conclusion

Existing EPTS formula is not statistically significantly predictive in pediatric kidney recipients

Summary of discussion:

A member inquired if there is hard data showing how EPTS has affected pediatric kidney allocation. Pediatric patients would be competing with older patients who have an EPTS of less than 20 percent and are getting kidneys that have a kidney donor profile index of less than 20 percent. The member clarified by inquiring, if EPTS was included in current pediatric kidney allocation, is there data on how many more pediatric patients would have received a kidney.

The Chair stated that there may be previous literature; however, for this discussion the Kidney and Pancreas Continuous Distribution Workgroup is thinking about how to include EPTS in continuous distribution, but for adults they are interested in using the EPTS so in this new system going forward would EPTS be appropriate to use for pediatric recipients.

Next Steps:

Staff stated that they will reach out via email to members with the EPTS recommendation for pediatric kidney recipients in the kidney and pancreas continuous distribution framework. The Committee will briefly review the recommendation at the beginning of their next meeting to reach a consensus.

There was no further discussion.

The meeting was adjourned.

Upcoming Meeting

- August 17, 2022

Attendance

- **Committee Members**
 - Emily Perito
 - Evelyn Hsu
 - Brian Feingold
 - Caitlin Shearer
 - Daniel Ranch
 - Geoffrey Kurland
 - Gonzalo Wallis
 - Jennifer Lau
 - Johanna Mishra
 - Kara Ventura
 - Meelie DebRoy
 - Namrata Jain
 - Neha Bansal
 - Reem Raafat
 - Shantavia Edmonds
 - Shellie Mason
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Rebecca Brookman
 - Matt Cafarella
 - Betsy Gans
 - Eric Messick
 - Kristin Cuff
 - Laura Schmitt
 - Laura Mauk
 - Samantha Weiss
 - Sara Rose Wells
 - Susan Tlusty
- **Other Attendees**
 - Melissa McQueen